

CLAIMS:

1. A pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or polypeptide and colloidal particles, said particles comprising approximately 1-20 mole percent of an 5 amphipathic lipid derivatized with a biocompatible hydrophilic polymer, wherein said protein or polypeptide is selected from the group consisting of:
 - (a) proteins or polypeptides capable of externally binding said colloidal particles;
 - (b) proteins or polypeptides capable of binding polymers of the polyalkylether, polylactic and polyglycolic acid families; and
 - (c) proteins or polypeptides that include a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;wherein said protein or polypeptide is not Factor VIII (FVIII), and wherein said protein or polypeptide is not encapsulated in said colloidal particles.
- 15 2. The pharmaceutical composition of Claim 1 wherein the colloidal particles are substantially neutral and the polymer carries substantially no net charge.
3. The pharmaceutical composition of Claim 1 wherein the colloidal particle 20 has a mean particle diameter of between about 0.03 to about 0.4 microns.
4. The pharmaceutical composition of Claim 3 wherein the colloidal particle has a mean particle diameter of approximately 0.1 microns.
5. The pharmaceutical composition of any of Claims 1-4 wherein said 25 amphipathic lipid is a phospholipid from natural or synthetic sources.
6. The pharmaceutical composition of Claim 5 wherein said amphipathic lipid is phosphatidylethanolamine (PE).
7. The pharmaceutical composition of any of Claims 1-4 wherein said amphipathic lipid is a carbamate-linked uncharged lipopolymer.

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8. The pharmaceutical composition of Claim 7 wherein said amphipathic lipid is aminopropanediol distearoyl (DS)
9. The pharmaceutical composition of Claim 1 wherein said colloidal particles further comprise a second amphipathic lipid obtained from either natural or 5 synthetic sources.
10. The pharmaceutical composition of Claim 9 wherein said second amphipathic lipid is phosphatidylcholine.
11. The pharmaceutical composition of Claim 9 wherein cholesterol is supplemented to the composition.
- 10 12. The pharmaceutical composition of Claim 1 wherein said biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.
13. The pharmaceutical composition of Claim 12 wherein said biocompatible hydrophilic polymer is polyethylene glycol.
- 15 14. The pharmaceutical composition of Claim 13 wherein the polyethylene glycol has a molecular weight of between about 500 to about 5000 daltons.
15. The pharmaceutical composition of Claim 14 wherein the polyethylene glycol has a molecular weight of approximately 2000 daltons.
16. The pharmaceutical composition of Claim 1 wherein the protein or polypeptide 20 is selected from the group consisting of prothrombin, Factor VIIa, Factor X, Factor V, Factor IX (FIX), granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Copaxone.
17. The pharmaceutical composition of Claim 16 wherein the polypeptide is 25 Copaxone and the composition is used for the treatment of a disease selected from multiple sclerosis, diabetic neuropathy, senile dementia, Alzheimer's disease, Parkinson's Disease, facial nerve (Bell's) palsy, glaucoma, Huntington's chorea, amyotrophic lateral sclerosis, status epilepticus, non-arteritic optic neuropathy, and vitamin deficiency.

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18. The pharmaceutical composition of Claim 16 wherein the polypeptide is Factor VIIa and the composition is used hemophilia patients with inhibitors and for the treatment of trauma bleeding.
19. The pharmaceutical composition of Claim 1 wherein the protein or polypeptide 5 comprises an amino acid consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, wherein X is any amino acid.
20. Method of treatment of a patient suffering from hemophilia comprising administrating to said patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or 10 polypeptide effective in the treatment of hemophilia and colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein said protein or polypeptide is selected from the group consisting of:

 - (a) proteins or polypeptides capable of externally binding said colloidal 15 particles; and
 - (b) proteins or polypeptides capable of binding polymers of the polyalkylether, polylactic and polyglycolic acid families; and
 - (c) proteins or polypeptides that include a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, 20 L, I, V, E and Q have their standard meanings;

wherein said protein or polypeptide is not Factor VIII (FVIII), and wherein said said protein or polypeptide is not encapsulated in said colloidal particles.
21. A method according to Claim 20 wherein said patient has developed 25 inhibitor antibodies to said protein or polypeptide.
22. Use of a colloidal particle in the preparation of a pharmaceutical composition for parenteral administration for treatment of a patient suffering from hemophilia comprising a therapeutically effective amount of a protein or polypeptide and colloidal particles, said particles comprising

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approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein said protein or polypeptide is selected from the group consisting of:

- 5 (a) proteins or polypeptides capable of externally binding said colloidal particles; and
- (b) proteins or polypeptides capable of binding polymers of the polyalkylether, polylactic and polyglycolic acid families; and
- (c) proteins or polypeptides that include a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;

wherein said protein or polypeptide is not Factor VIII (FVIII),

and wherein said said protein or polypeptide is not encapsulated in said colloidal particles.

15 23. A use according to Claim 22 wherein said patient has developed inhibitor antibodies to said protein or polypeptide.

24. Use of a colloidal particle in the preparation of a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or polypeptide and colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein said protein or polypeptide is selected from the group consisting of:

- (a) proteins or polypeptides capable of externally binding said colloidal particles; and

- (b) proteins or polypeptides capable of binding polymers of the polyalkylether, polylactic and polyglycolic acid families; and

- (c) proteins or polypeptides that include a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;

30 wherein said protein or polypeptide is not Factor VIII (FVIII),

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and wherein said protein or polypeptide is not encapsulated in said colloidal particles.

25. Method of treatment of a patient suffering from a disease comprising administrating to said patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or polypeptide effective in the treatment of the disease and colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein said protein or polypeptide is selected from the group consisting of:

- 10 (a) proteins or polypeptides capable of externally binding said colloidal particles; and
- (b) proteins or polypeptides capable of binding polymers of the polyalkylether, polylactic and polyglycolic acid families; and
- (c) proteins or polypeptides that include a consensus sequence of S/T-X-15 L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;

wherein said colloidal particles and said protein or polypeptide are administered separately,

and wherein said said protein or polypeptide is not encapsulated in said 20 colloidal particles.

26. The method of claim 25 wherein said protein or polypeptide is not Factor VIII (FVIII).

27. The method of claim 25 wherein said colloidal particle is a liposome and said protein or polypeptide is Factor VIII (FVIII).